TERUMO

K083747

Submitter Information:

This submission was prepared in November 2008 by:

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AUG 20 2009

This submission was prepared for:

Terumo Cardiovascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Registration #1124841

Device Names/Classifications:

Proprietary Name	Classification Name	Common Name
Terumo Pall AL3X Pediatric Arterial Filter	Cardiopulmonary Bypass Arterial Line Blood Filter (Code: DTM)	Arterial Filter

Predicate Device(s):

The device submitted in this 510(k) maintains characteristics that are substantially equivalent to the following devices:

- Terumo's Capiox® AF02X Arterial Filter – K011804
- Terumo Pall AL8X Arterial Filter K032128

Intended Use:

The Terumo Pall AL3X Pediatric Arterial Filter is indicated for use in cardiopulmonary bypass procedures for the removal of micro-emboli greater than 40 microns in size, including gas emboli, fat emboli, and aggregates composed of platelets, red blood cells, and other debris from the arterial line and where the flow rate will not exceed 3 liters per minute.

The device may be used in procedures lasting up to 6 hours in duration.

Principles of Operation and Technology:

The Terumo Pall AL3X Pediatric Arterial Filter performs its functions using two basic forms of technology. As a filtration device, particulates in the blood stream are captured and removed from the blood flow as blood passes through a filter mesh material that is contained within the device housing. The filter establishes a physical barrier that entraps particulate matter and prevents it from moving downstream of the arterial filter assembly.

As an air-removal device, the Terumo Pall AL3X Pediatric Arterial Filter is designed so that air is removed from the blood stream as a result of centripetal force. The blood inlet port of the device is positioned on the upper-side axis of the polycarbonate housing, thereby creating a spiral blood flow pattern as blood enters the device. Because the blood flows through the device in a

spiral motion, centripetal forces cause the air bubbles to migrate towards the top of the housing assembly where air can be manually purged from the circuit.

Design and Materials:
The materials that are used in the construction of the Terumo Pall AL3X Pediatric Arterial Filter include polycarbonate, polyester screen, polypropylene, acrylonitrile-butadiene styrene and X-Coating™.

Performance Evaluations:
Terumo Cardiovascular Systems, in conjunction with Pall Medical Corporation, conducted the following *in-vitro* performance evaluations to demonstrate the functional equivalence of the AL3X Arterial Filter to the predicate AF02X Arterial Filter.

The following tests were performed, and are presented on the ensuing pages:

- Filtration Efficiency
- Air Removal Efficiency
- Hemolytic Effect Upon Cellular Components of Blood
- Pressure Drop
- Tubing Connection Strength
- Static Priming Volume
- Mechanical Integrity/Leakage Evaluation

Substantial Equivalence Comparison:
In demonstrating substantial equivalence of the Terumo Pall AL3X Arterial Filter to the predicate AF02X device, a comparative study and/or assessment was performed in each of the following areas:

- Intended use
- Duration of use/6-hour use
- Product labeling
- Operation and technology of the devices
- Product design
- Materials used in device construction
- Design performance

The Terumo Pall AL8X device is referenced as a predicate device with respect to packaging equivalence and biocompatibility equivalence.

Substantial Equivalence Statement:
The Terumo Pall AL3X Pediatric Arterial Filter is substantially equivalent in intended use, duration of use, labeling, operation and technology, design, materials, and performance to the predicate Terumo AF02X Arterial Filter device. Additionally, the AL3X device and predicate AL8X device utilize equivalent packaging schemes.

Additional Safety Information:
- Sterilization conditions for the Terumo Pall AL3X Pediatric Arterial Filter will be validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

Terumo further asserts that the ethylene oxide residues will not exceed stated or implied maximum residue limits at the time of product distribution.

- The X-Coating material that is applied to the blood-contacting surfaces of the devices was evaluated in an *in-vivo* animal study conducted by Terumo Cardiovascular and Sierra Biomedical Laboratories in 1999. No adverse conditions were noted.

Conclusion:

Based upon the comparative studies and analyses, Terumo Cardiovascular Systems concludes that the Terumo Pall AL3X Pediatric Arterial Filter is ***substantially equivalent*** to the predicate Terumo AF02X Arterial Filter device with respect to safety and effectiveness – and the AL8X device with respect to packaging. It is further concluded that any recognized differences noted during the assessments do not raise new issues of patient/user safety or product effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

AUG 20 2009

Terumo Cardiovascular Systems Corp.
c/o Mr. Garry Courtney
Regulatory Affairs/Quality Systems Manager
125 Blue Ball Rd.
Elkton, MD 21921

Re: K083747
Terumo Pall AL3X Pediatric Arterial Filter
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: Class II (two)
Product Code: DTM
Dated: July 10, 2009
Received: July 15, 2009

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the [kit/tray] have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Donna R. Vahmer

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

TERUMO

SECTION 4
Indications for Use

510(k) Number (if known): ~~Unknown at time of submission~~ K083747

Device Name: Terumo Pall AL3X Pediatric Arterial Filter

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The device may be used in procedures lasting up to 6 hours in duration.

Prescription Use ___XX___ OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diane R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083747